Interview Summary	Application No.	Applicant(s)	
	09/585,541	GENTZ ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Bradley L. Sisson*. (3)*Peter A. Jackman*.

(2) *Eric Steffe*. (4)_____.

Date of Interview: *12 June 2002* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Draft amendment of claims received 03 June 2002* .

Claim(s) discussed: *1* .

Identification of prior art discussed: *US Patent 6,238,888 B1* .

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

B. L. Sisson

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Mr. Sisson indicated concern over the breadth of scope for the peptide sequence recited in claim 1, drawing attention to the use of the term "comprising" which seemingly opens the claim up to include any and all manner of flanking sequences, including, but not limited to sequences found in the native protein. Mr. Sisson noted that prior discussion acknowledged the specification suggesting the linkage of PEG to the polypeptide, but that the polypeptide-PEG complex had not actually been produced. Mr. Steffe indicated that a formal version of the draft response will be submitted on about June 14, 2002 and that it will contain indications of where adequate support for additional polypeptides can be found in the subject application as well as in priority documents.
Agreement was reached in that a terminal disclaimer will be filed over US Patent 6,238,888 B1. Mr. Steffe indicated that Claim 44 will be amended so to address the aspect of "high molecular weight," in that the phrase will be replaced with the term "Carbomers".

Draft

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Facsimile Cover Sheet

urgent ☐ return reply requested ☐ original will be sent as confirmation ☐

DATE: June 3, 2002 **FAX NO.:** (703) 746-5020

PAGES: 9 (including this cover sheet)

TO: U.S. Patent and Trademark Office

ATTN: Examiner Bradley Sisson

FROM: Peter A. Jackman, Esq. PAJ

RE: Draft Claims for U.S. Appl. No. 09/585,541; Filed June 2, 2000
For: **Keratinocyte Growth Factor-2 Formulations**
Inventors: Gentz *et al.*

OUR REF: 1488.1030004/EKS/PAJ

MESSAGE

Attached please find a draft set of claims.

SKGF_DC1:18801.1

please sign and return this page as acknowledgment of receipt

If any portion of this transmission is not received clearly or in full, contact us at any of the following numbers:

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DRAFT CLAIM AMENDMENTS
Our Ref: 1488.1030004

Gentz *et al.*
U.S. Appl. No. 09/585,541

DRAFT AMENDMENTS

1. (Once amended) A pharmaceutical composition, comprising:
(a) a [KGF-2] polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2 in a concentration range of about 0.02 to about 40 mg/ml (w/v);
(b) a buffer having a buffering capacity of about pH 5.0 to about pH 8.0 at a concentration range of about 5 mM to about 50 mM; and
(c) a pharmaceutically acceptable diluent to bring the composition to a designated volume; and
(d) a preservative selected from the group consisting of m-cresol, chlorobutanol, and a mixture of methyl paraben and propyl paraben;
or a reaction product thereof,
wherein said polypeptide stimulates epithelial cell proliferation.

2. The pharmaceutical composition of claim 1, further comprising one or more of:
(a) a chelating agent at a concentration range of about 0 mM to about 10 mM; and
(b) a tonicifier at a concentration range of about 0 mM to about 150 mM.

3. The pharmaceutical composition of claim 2, wherein said tonicifier is selected from the group consisting of NaCl, glycine, sucrose, mannitol, and mixtures thereof.

4. The pharmaceutical composition of claim 1, further comprising one of:
1. about 0.5% to about 2% w/v glycerol,
2. about 0.1% to about 1% w/v methionine, or
3. about 0.1% to about 2% w/v monothioglycerol.

5. (Once amended) The pharmaceutical composition of claim 1, wherein said [KGF-2] polypeptide is present in a concentration range of about 0.05 to about 30 mg/ml (w/v).

6. (Once amended) The pharmaceutical composition of claim 5, wherein said [KGF-2] polypeptide is present in a concentration range of about 0.1 to about 20 mg/ml (w/v).

7. (Once amended) The pharmaceutical composition of claim 6, wherein said [KGF-] polypeptide is present in a concentration range of about 0.2 to 4 mg/ml (w/v).

8. Canceled.

9. The pharmaceutical composition of claim 1, wherein said diluent is water.

10. The pharmaceutical composition of claim 2, wherein said chelating agent is EDTA at a concentration of about 1 mM, and said tonicifier is present at a concentration of about 125 mM.

11. The pharmaceutical composition of claim 1, wherein said pH is from about pH 5.5 to about pH 6.5.

12. The pharmaceutical composition of claim 11, wherein said pH is about pH 6.0.

13. The pharmaceutical composition of claim 1, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

14. The pharmaceutical composition of claim 13, wherein said buffer is a phosphate, acetate or citrate salt.

15. The pharmaceutical composition of claim 13, wherein said buffer is a citrate salt.

16. The pharmaceutical composition of claim 1, wherein said buffer is present in a concentration range of about 5 mM to about 30 mM.

17. The pharmaceutical composition of claim 16, wherein said buffer is a citrate salt present in a concentration of from about 10 mM to about 20 mM.

18. The pharmaceutical composition of claim 1, further comprising a stabilizing amount of one or more of (a) an antioxidant or (b) a thiol-compound.

19. The pharmaceutical composition of claim 1, wherein said composition is maintained at a temperature at or below -20 C.

20. (Once amended) The pharmaceutical composition of claim 1, wherein said [KGF-2Δ 33] polypeptide is selected from the group consisting of: (i) Ser (69) - Ser (208) of SEQ ID NO:2; (ii) Ser (69) - Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii) [KGF-2Δ33 polypeptide having an N-terminal methionine, KGF-2Δ33 polypeptide lacking an N-terminal methionine, and a mixture thereof].

21. The pharmaceutical composition of claim 1, further comprising a bulking agent.

22. The pharmaceutical composition of claim 21, wherein said bulking agent is selected from the group consisting of sucrose, glycine, mannitol, trehalose, and mixtures thereof.

23. The pharmaceutical composition of claim 22, wherein said bulking agent is sucrose or a mixture of sucrose and glycine.

24. The pharmaceutical composition of claim 2, further comprising a bulking agent.

25. The pharmaceutical composition of claim 22, wherein said bulking agent is present in a concentration of about 2% to about 10% w/v.

26. The pharmaceutical composition of claim 22, wherein said bulking agent is 5% mannitol, 7% sucrose, 8% trehalose, or 2% glycine + 0.5% sucrose.

27. The pharmaceutical composition of claim 21, wherein said pH is about pH 6.2.

28. The pharmaceutical composition of claim 21, wherein said diluent is water.

29. The pharmaceutical composition of claim 21, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

30. The pharmaceutical composition of claim 29, wherein said buffer is a phosphate or citrate salt.

31. The pharmaceutical composition of claim 30, wherein said buffer is a citrate salt.

32. The pharmaceutical composition of claim 28, wherein over 90% of the water is removed by lyophilization.

33. The pharmaceutical composition of claim 32, which is reconstituted in with an amount of sterile water effective to maintain isotonic conditions of about 290 mOsm.

34. Canceled.

35. Canceled.

36. The pharmaceutical composition of claim 21, wherein said buffer is added in a concentration from about 5 mM to about 50 mM.

37. The pharmaceutical composition of claim 36, wherein said buffer is citrate at a concentration of about 10 mM.

38. The pharmaceutical composition of claim 21, further including a stabilizing amount of one or more of (g) an antioxidant, or (h) a thiol-compound.

39. The pharmaceutical composition of claim 32, wherein said composition is reconstituted in sterile water containing a stabilizing amount of an antioxidant comprising: a) about 0.01% to about 2% w/v monothioglycerol, b) about 0.01% to about 2% w/v ascorbic acid, c) about 0.01% to about 2% w/v methionine or d) combinations thereof.

40. The pharmaceutical composition of claim 1, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

41. The pharmaceutical composition of claim 40, wherein said thickening agent is present in an amount effective to raise the viscosity to about 50 to about 1,000 cps.

42. The pharmaceutical composition of claim 41, wherein said thickening agent in an amount effective to raise the viscosity to about 200 to about 300 cps.

43. The pharmaceutical composition of claim 40, wherein said thickening agent is present in a concentration of 0 to 5% (w/w).

44. The pharmaceutical composition of claim 40, wherein said thickening agent is a water soluble etherified cellulose or a high molecular weight polymer of acrylic acid cross-linked with allylsucrose or an allyl ether of pentaerythritol.

45. The pharmaceutical composition of claim 44, wherein said etherified cellulose is an alkyl cellulose, hydroxyalkyl cellulose, carboxyalkyl cellulose or alkylhydroxyalkyl cellulose.

46. The pharmaceutical composition of claim 40, wherein said etherified cellulose is methylcellulose, hydroxyethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose.

47. The pharmaceutical composition of claim 46, wherein said etherified cellulose derivative has a molecular weight of about 50,000 to about 700,000 and is present in a concentration of about 0 to about 20% by weight.

48. The pharmaceutical composition of claim 47, wherein said etherified cellulose derivative has a molecular weight of about 80,000 to about 240,000 and is present in a concentration of about 2% to about 8% by weight.

49. The pharmaceutical composition of claim 42, wherein said buffer is citrate in a concentration of about 10 mM to about 50 mM.

50. The pharmaceutical composition of claim 49, wherein said buffer is citrate in a concentration of about 10 mM to about 20 mM citrate.

51. The pharmaceutical composition of claim 49, wherein said bulking agent is sucrose in a concentration of about 0.01% to about 5% sucrose.

52. The pharmaceutical composition of claim 51, wherein said thickening agent is added directly to a liquid formulation and thereafter lyophilized.

53. The pharmaceutical composition of claim 51, wherein said thickening agent is added to a lyophilized formulation by reconstituting said formulation by adding a suitable diluent having a thickening agent dissolved therein.

54. The pharmaceutical composition of claim 21, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

55. The composition of claim 1, further comprising a gelling agent in an amount effective to raise the viscosity to about 0.1 to about 10,000 cps at room temperature.

56. The composition of claim 21, further comprising a gelling agent in an amount effective to raise the viscosity to about 0.1 to about 10,000 cps at room temperature.

57. The composition of claim 55, wherein said gel forming agent is a water-soluble polymer capable of forming a viscous aqueous solution, or non-water soluble, water-swellable polymer capable of forming a viscous solution.

58. The composition of claim 57, wherein said gel forming agent is a high molecular weight polymer selected from the group consisting of vinyl polymer, polyoxyethylene-polyoxypropylene copolymer, polysaccharide, protein, poly(ethylene oxide), acrylamide polymer or a salt thereof.

59. The composition of claim 58, wherein said gel forming agent is (1) a vinyl polymer selected from the group consisting of polyacrylic acid, polymethacrylic acid, polyvinyl pyrrolidone polyvinyl alcohol, and salts and esters thereof; or (2) a polysaccharide selected from the group consisting of a cellulose derivative, a glycosaminoglycan, agar, pectin, alginic acid, dextran, -amylose, amylopectin, chitosan, and salts esters thereof.

60. The composition of claim 58, wherein said gel forming agent is a glycosaminoglycan selected from the group consisting of hyaluronic acid, chondroitin, chondroitin-4-sulfate, heparan sulfate, heparin and salts and esters thereof.

61. The composition of claim 60, wherein said glycosaminoglycan is present in combination with collagen, gelatin, or fibronectin.

62. The composition of claim 58, wherein said gel forming agent is an acrylamide polymer selected from the group consisting of a polyacrylamide or a polymethacrylamide.

63. The composition of claim 58, wherein said gel forming agent is a polyoxyethylene-polyoxypropylene block copolymer.

64. The composition of claim 63, which comprises about 10 to about 60% by weight of a polyoxyethylene-polyoxypropylene block copolymer having an average molecular weight of about 500 to 50,000.

65. The composition of claim 64, which comprises about 14 to about 18% by weight of a polyoxyethylene-polyoxypropylene block copolymer having a molecular weight in the range 1,000 to 15,000.

66. (Once amended) The pharmaceutical composition of claim 1, wherein said [KGF-2] polypeptide is present in a concentration range of about 0.01 mg/ml to about 10 mg/ml (w/v).

67. Canceled.

68. Canceled.

69. Canceled.

70. Canceled.

71. The pharmaceutical composition of claim 1, further comprising one of:
(a) lysine;
(b) hydroxypropyl- -cyclodextrin; and
(c) sulfated- -cyclodextrin;
or combinations thereof.

72. The pharmaceutical composition of claim 1, wherein said preservative is a mixture of methyl paraben and propyl paraben.

73. The pharmaceutical composition of claim 72, wherein said composition comprises 0.18% methyl paraben and 0.02% propyl paraben.

74. (Once amended) A pharmaceutical composition comprising:
(a) about 1.0 mg/ml [KGF-2] of a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2;
(b) 20 mM citrate, pH 5-5.5; and
(c) 0.01% polysorbate 80,
wherein said polypeptide stimulates epithelial cell proliferation.

75. The pharmaceutical composition of claim 74, further comprising 1 mM EDTA.

76. (Once amended) A pharmaceutical composition comprising:
(a) about 3.3 mg/ml [KGF-2] of a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2;
(b) 10 mM sodium citrate
(c) 20 mM sodium chloride;
(d) 1 mM EDTA
(e) 2% w/v glycine;
(f) 0.5% w/v sucrose;
(g) water; and
(h) pH about 6.2;
or a reaction product thereof,
wherein said polypeptide stimulates epithelial cell proliferation.

77. The pharmaceutical composition of claim 77, wherein over 90% of the water is removed by lyophilization.

78. A pharmaceutical composition comprising:
(a) about 1.0 mg/ml [KGF-2] of a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2;
(b) 10 mM sodium citrate;
(b) 0.46% hydroxyethylcellulose;
(c) 7% sucrose;
(d) 20 mM sodium citrate;
(e) 20 mM sodium chloride;
(f) 1 mM EDTA; and
(g) pH about 6.2;
or reaction products thereof,
wherein said polypeptide stimulates epitheljal cell proliferation.

79. (New) The pharmaceutical composition of claim 74, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) - Ser (208) of SEQ ID NO:2; (ii) Ser (69) - Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

80. (New) The pharmaceutical composition of claim 76, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) - Ser (208) of SEQ ID NO:2; (ii) Ser (69) - Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

81. (New) The pharmaceutical composition of claim 78, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) - Ser (208) of SEQ ID NO:2; (ii) Ser (69) - Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

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